

REMARKS

Reconsideration of this application and entry of this Amendment is respectfully requested. Claims 1-22 have been cancelled and replaced by new claims 23-29, in a sincere effort to more precisely recite the invention and expedite the prosecution of this application to allowance.

Support for claims 23-29 appears on page 2, lines 13-16, page 3, lines 1-11, Fig. 1 and the accompanying text on pages 4-7 of the specification. No new matter has been added.

The objection to claims 18-22 as being informal is believed obviated in view of their cancellation.

With regard to the inventorship, the subject matter of all claims was commonly owned at the time the invention covered herein was made.

Applicant respectfully submits that new claims 23-29 are patentably distinct over the references relied upon by the Examiner in the rejection of claims 18-22, that is U.S. Patent No. 5,106,187 to Bezanson in view of U.S. Patent No. 5,895,764 to Sklar.

Bezanson's invention relates to an apparatus for the detection and analysis of small particles and fluids by using conductivity, scattering and fluorescent detectors to create signals that are stored as separate wave forms so that the various wave forms relating to a single particle can be used

as a composite source of information to establish the identity and characteristics of a particle (column 1, lines 7-10 and 40-46).

Notably, Bezanson neither discloses nor suggests a method for improving the precision in counting the number of particles or cells suspended in a volume of test sample that can range from low particle/cell counts to high particle/cell counts.

Applicant's claimed invention is accomplished by a variable flow rate method which comprises delivering a sheath stream of the test sample at a first volumetric flow rate to detection means for counting the number of particles or cells in the test sample, wherein the sheath stream has a cross-sectional diameter adapted to deliver to the detection means substantially one particle or cell of the test sample at a time.

The detection means then makes an initial count of the particles or cells of the test sample per unit time.

The initial count of the number of cells or particles in the test sample is then compared to a reference value and the flow rate of the test sample is then adjusted to a second volumetric flow rate based on the comparative number of cells or particles in the test sample compared to the reference value. This readjusted flow rate then enables the detection means to more precisely count the particles or cells of the test sample.

This invention has particular applicability in the clinical analysis of test samples, particularly hematology test samples wherein it is important to obtain precise counts of the cells or particles. See page 1 of the specification, lines 3-5 and 13-20.

One of the disadvantages of the prior art methodology used to count particles is their operation within a very limited dynamic range such that at low cell counts, precision suffers and at high cell counts, several cells pass at the same time through the detection device and are counted as one cell thereby limiting the utility of such methods.

In addition most of the known methods deliver a fixed volume of a diluted sample solution at a fixed rate for counting purposes. When cell counts are low, repetitive tests are usually needed to improve precision. Where cell counts are high in the test samples, the maximum cell capacity is too low for very high cell counts (at page 1, line 21 to page 2, line 10).

The present invention provides for a variable rate volumetric particle count method which enables precise cell counts and readily adapts to test samples having a low numbers of particles/cells ranging to high numbers of particles/cells.

Bezanson is inapplicable to the present invention because it does not recognize the problem involved nor does it disclose or suggest

methodology to achieve the purpose of the claimed invention. Rather, Bezanson's invention is solely directed to methodology that only enables the identification of certain types of particles (column 4, lines 7-12). Accordingly, reconsideration and withdrawal of Bezanson is respectfully requested.

The combination of U.S. Patent No. 5,895,764 to Sklar et al with Benzanson does not resolve the deficiencies of Bezanson, but rather compounds them. Sklar's invention is related to flow cytometers, which are valuable tools for mechanistic studies of molecular interactions, such as cell function (column 1, lines 5-7), but does not have any application to applicant's claimed invention. The objective of Sklar is to control sheath flow in a flow cytometer to enhance and clarify particle analysis (column 2, lines 37-39).

Therefore, the combination of Sklar with Bezanson does not obviously suggest applicant's claimed invention because neither of these patents have any relation to a method for adjusting the flow rate of test samples to obtain more precise counts of the cells/particles in samples that range from low cell/particle counts to high cell/particle counts.

Accordingly, reconsideration and withdrawal of the Sklar reference is respectfully requested.


In view of the above new claims and arguments distinguishing the Bezenson and Sklar patents from the claimed invention, it is respectfully submitted that this application is in condition for allowance and such favorable action is respectfully requested.

Rodman & Rodman
7 South Broadway
White Plains, NY 10601

Telephone: (914) 949-7210
Facsimile: (914) 993-0668

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Respectfully submitted,



Charles B. Rodman
Registration No. 26,798
Attorney for Applicants